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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAI‘I

THAD ESTRADA,

Plaintiff,

vs.

USPLABS, LLC, GNC CORPORATION and DOES 1-500, Inclusive,

Defendants.

CIVIL NO. 15-00228

COMPLAINT; DEMAND FOR JURY TRIAL; SUMMONS

1. Negligence (Against USP)
2. Negligence (Against GNC)
3. Strict Products Liability – Manufacturing Defect (Against USP)
4. Strict Products Liability – Manufacturing Defect (Against GNC)
5. Strict Products Liability – Defective Design (Against USP)
6. Strict Products Liability – Defective Design (Against GNC)
7. Strict Products Liability – Failure to Warn (Against USP)
8. Strict Products Liability – Failure to Warn (Against GNC)
9. Breach of Implied Warranty (Against USP)
10. Breach of Implied Warranty (Against GNC)

COMPLAINT

Plaintiff THAD ESTRADA, by and through his attorney of record, brings this action against Defendants USPLABS, LLC, GNC CORPORATION, and DOES 1-500, (collectively, "DEFENDANTS"). Plaintiff alleges on information and belief, except for information based on personal knowledge, as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 in that the amount in controversy exceeds seventy-five thousand dollars ($75,000), exclusive of interest and costs, and Plaintiff and Defendants are resident citizens of different states.

2. Venue in this Court is proper pursuant to 28 U.S.C. §1391 in that a substantial part of the events or omissions giving rise to the claims asserted herein occurred in this District, and Defendants are subject to personal jurisdiction in this district.

DEFENDANT PARTIES

I. Product Designer, Marketer, and Distributor

3. Defendant USPLABS, LLC is a Texas corporation headquartered in Dallas, Texas, and was and is regularly engaged in the business of licensing, manufacturing, formulating, packaging, distributing,

and/or selling, either directly or indirectly, through third parties or related entities, non-prescription dietary supplements for sale to, and use by, members of the general public, and as a part of their business, said Defendant, directly or indirectly was and is engaged in the manufacturing/formulating/packaging/distributing/selling of purported nutritional/dietary supplements under the proprietary, trademarked names "OxyElite Pro Ultra Intense Thermo", "OxyElite Pro Super Thermo", and "OxyElite Pro Super Thermo Powder" (collectively "OxyElite Pro New Formula") in interstate commerce and in Hawai‘i, which Plaintiff ingested as alleged herein.

4. At all times herein alleged, each of the acts of the employees were on behalf of, for the benefit of, at the direction of, and at the behest of USP and were ratified by USP. Further, each of the acts of the employees were done pursuant to and in accordance with corporate policy.

5. Upon information and belief, at all relevant times, USPLabs, LLC was present and doing business in the State of Hawai‘i.

6. At all relevant times, USPLabs, LLC transacted, solicited, and conducted business whether through retail stores or through internet merchants in the State of Hawai‘i and derived substantial revenue from such business.

7. At all relevant times, USPLabs, LLC expected or should have expected that its acts would have consequences within the United States of America and within the State of Hawai‘i.

II. Retailers

8. Defendant GNC CORPORATION (“GNC”) is a Delaware corporation with its principal place of business located in Pittsburgh, Pennsylvania. Defendant GNC conducted regular and sustained business in the State of Hawai‘i and throughout the nation, including the sale of OxyElite Pro New Formula by its retail outlets, affiliates and franchisees. Defendant GNC was regularly engaged in the business of packaging, distributing, and/or selling, either directly or indirectly, through third parties or related entities, non-prescription nutritional/dietary supplements for sale to, and use by, members of the general public, and as a part of their business said Defendant sold the OxyElite Pro New Formula purchased by, ingested by and causing harm to Plaintiff as alleged herein.

9. At all times herein alleged, each of the acts of the employees of GNC were on behalf of, for the benefit of, at the direction of, and at the behest of GNC and were ratified by GNC. Further, each of the acts of the GNC employees were done pursuant to and in accordance with corporate policy.

10. The true names or capacities, whether individual, corporate, or otherwise, of Defendants DOES 1 through 500, inclusive, are unknown to Plaintiff who is therefore ignorant of the true names and sues said Defendants by such fictitious names. Plaintiff believes and alleges that each of the Defendants designated herein by fictitious names is in some manner legally responsible for the events and happenings herein referred to and caused damages proximately and foreseeably to Plaintiff as alleged herein.

11. At all times hereinafter alleged, "DEFENDANTS" or "All DEFENDANTS" include all herein named Defendants as well as Defendants DOES 1 through 500, inclusive.

12. At all times herein alleged, each of the DEFENDANTS was the agent, servant, partner, aider and abettor, co-conspirator and joint venturer of each of the remaining DEFENDANTS herein and was at all times operating and acting within the course, purpose and scope of said agency, service, employment, partnership, conspiracy and joint venture and rendered substantial assistance and encouragement to the other DEFENDANTS, knowing that their conduct constituted a breach of duty owed to Plaintiff.

PLAINTIFF THAD ESTRADA

13. At all relevant times, Plaintiff THAD ESTRADA was a resident of the State of Hawai'i.

14. Before purchasing OxyElite Pro Super Thermo and OxyElite Pro Super Thermo Powder, Plaintiff was exposed to the advertising and marketing of USP and GNC. Plaintiff relied on the representations and warranties from USP and GNC made therein in making his decision to purchase OxyElite Pro Super Thermo and OxyElite Pro Super Thermo Powder, believing they would be safe and effective for their advertised use and relying on the expertise of USP and GNC. Had Plaintiff known OxyElite Pro Super Thermo and OxyElite Pro Super Thermo Powder were not safe and not effective for their advertised use he would not have purchased them and would not have used them.

15. In or about June or July 2013 until September 2013, Plaintiff ingested OxyElite Pro Super Thermo Powder purchased from GNC. In or about September 2013, Plaintiff ingested OxyElite Pro Super Thermo purchased from GNC.

16. At no time did Plaintiff take more than the recommended dosing regimen contained in OxyElite Pro Super Thermo and OxyElite Pro Super Thermo Powder.

17. In or about late September 2013, after taking the recommended dosing of and as a result of OxyElite Pro Super Thermo and OxyElite Pro Super Thermo Powder manufactured at the behest of USP, designed by USP, and marketed and sold by USP and GNC, Plaintiff suffered acute non-viral, toxic hepatitis/liver failure and related injuries.

FACTUAL BACKGROUND

The OxyElite Product

18. There are three versions of the new OxyElite product including: OxyElite Pro Ultra Intense Thermo, OxyElite Pro Super Thermo, and OxyElite Pro Super Thermo Powder (collectively "OxyElite Pro New Formula"). OxyElite Pro Super Thermo is a trademarked product designed, marketed, manufactured, distributed and sold by USP, either directly or at the direction and behest of USP. OxyElite Pro Super Thermo contains the following ingredients in its Proprietary Blend: Bauhinia Purpurea L. (Leaf and Pod) Extract, Aegeline, Norcoclaurine HCL, Hemerecallis Fulva (Flower) Heat Concentrated Extract, Yohimbe (Pausinystalia Johimbe) (Bark) Extract (AlphaShred). It also contains caffeine.

19. Here is a true and accurate photo of OxyElite Pro Super Thermo:

20. Each of the OxyElite Pro New Formula products are dangerous and untested dietary supplements that causes hepatic injuries, ranging from acute, mild liver dysfunction to hepatitis and liver failure requiring liver transplantation, or death.

21. Additionally, each of the OxyElite Pro New Formula products do not work.

22. OxyElite Pro New Formula is sold through retailers in Hawai‘i and across the United States.

*USP Fails to Learn Its Lesson from **Prior** Formulations of OxyElite, Which Contained DMAA, a Dangerous Chemical*

23. 1,3-Dimethylamylamine (known as DMAA) was an active ingredient contained in a former formulation of OxyElite (hereinafter "OxyElite with DMAA") manufactured, marketed, distributed, and sold by USP and GNC.

24. DMAA is an aliphatic amine compound that has properties mimicking those of the endogenous neurotransmitters of the sympathetic nervous system. As such, it belongs to a group of compounds known as "sympathomimetics." Members of this class include ephedrine and the amphetamines.

25. Sympathomimetic compounds were originally developed in the 19th century as drugs for the treatment of cold symptoms. Compounds capable of constricting blood vessels were actively sought. First cocaine, then epinephrine, and in 1925 ephedrine, were used for this purpose.

26. In 1943, DMAA was introduced as a nasal decongestant by Eli Lilly under the trade name of Forthane. For unexplained reasons Lilly voluntarily withdrew Forthane from the market in 1983. No other prescription or over-the-counter drugs or dietary supplements used DMAA from 1983 until approximately 2005. In 2005, Patrick Arnold, a chemist convicted for his role in the BALCO baseball steroid scandal, reintroduced DMAA as an over-the-counter dietary supplement with amphetamine-like qualities. It was marketed as an alternative to ephedrine. The use of DMAA in dietary supplements spread and eventually found its way into OxyElite with DMAA.

27. Animal testing in a variety of models demonstrated that DMAA was a potent pressor drug causing increases in blood pressure that are comparable to those observed after the administration of ephedrine. The structure of and mechanism by which DMAA increases blood pressure is thus similar to ephedrine. Dietary supplements containing ephedra, the natural form of ephedrine, were ordered off the market by the FDA in 2004, because the blood pressure and heart

rate effects were associated with a number of serious adverse events to users, including heart attack, stroke and death.

28. Even though USP knew OxyElite with DMAA was dangerous because it was a sympathomimetic that caused serious cardiovascular injuries in susceptible users, USP attempted to downplay or assuage health concerns regarding OxyElite with DMAA by claiming it was "safe and effective" as determined by university studies. However, not only did these studies not constitute reliable scientific or clinical proof, but the studies were funded by USP. On information and belief, the research team conducting DMAA studies has received $524,332 in funding from USPLabs. Moreover, even those studies found that the sympathomimetic effects of OxyElite with DMAA resulted in statistically significantly increased blood pressure.

29. Despite the lack of reliability or validity of the purportedly independent studies, the studies present a relatively consistent picture. DMAA, particularly when combined with caffeine or other agents, causes highly significant increases in blood pressure in healthy, resting individuals within one hour of consumption in a manner consistent with its known action as a vasoconstrictor. These sorts of changes should be anticipated to cause substantial and possibly dangerous increases in blood pressure during exercise (particularly weight lifting, cycling, or other resistance exercise). Vasoconstriction during exercise would

increase myocardial oxygen consumption leading to an increased risk for cardiovascular events like heart attack and stroke. In other words, the studies themselves, flawed as they are, demonstrate the dangerous and synergistic sympathomimetic effects of the DMAA formulation contained in Oxylite with DMAA.

30. In February 2012, under pressure from the Department of Defense after the death of two soldiers from DMAA, GNC agreed to pull its DMAA-containing products, including OxyElite with DMAA, from its stores on military bases. Nevertheless, GNC continued to market and sell DMAA products to consumers in its other retail stores and through its online website.

31. In fact, in a warning letter sent to USP, FDA expressed its opinion that OxyElite with DMAA is adulterated under §402(f)(1)(A) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §342, in that OxyElite with DMAA presents a significant or unreasonable risk of illness or injury under conditions of use recommended or suggested in labeling:

> . . . Oxy Elite Pro and Jack3d are adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) because they contain a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of

> such products into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). To the best of FDA's knowledge, there is no history of use or other evidence of safety establishing that dimethylamylamine will reasonably be expected to be safe as a dietary ingredient. In fact, dimethylamylamine narrows the blood vessels and arteries, which increases cardiovascular resistance and frequently leads to elevated blood pressure. This rise in blood pressure may increase the work of the heart such that it could precipitate a cardiovascular event, which could range from shortness of breath to tightening of the chest and/or a possible myocardial infarction (heart attack).

32. Notwithstanding significant and mounting evidence that OxyElite with DMAA posed significant health risks, USP did not recall OxyElite with DMAA. Despite the evidence of significant health risks, USP continued to downplay the true health risks involved with consuming OxyElite with DMAA.

33. Retailers like GNC joined in the misrepresentations about DMAA, by asserting in its marketing of OxyElite with DMAA that GNC conducts a review and has a requirement that the products it sells have labels that truthfully disclose health and safety issues and that the ingredients be safe. GNC represents that it exercises the highest standard of care in the nutritional supplement industry by "demanding truth in labeling, ingredient safety."

34. Not only did USP misrepresent the safety of OxyElite with DMAA, it maintained as against the entire medical community that the DMAA it used was a natural extract rather than synthetic. FDA denied that DMAA is a natural as opposed to synthetically-created compound.

35. In a letter addressed to USPLabs from FDA dated April 27, 2012, the Agency warned that it had received 42 adverse event reports on products containing DMAA, including cardiac disorders, nervous system disorders, and death. Other adverse events reported include rhabdomyolysis, kidney failure, liver injuries, seizures and other serious adverse events. Many of those adverse event reports were specifically for OxyElite with DMAA and stretch back to early 2010, if not earlier. Daniel Fabricant, director of FDA's Dietary Supplement Program (DSP) stated, "Before marketing products containing DMAA, manufacturers and distributors have a responsibility under the law to provide evidence of the safety of their products. They haven't done that and that makes the products adulterated."

36. On April 11, 2013, FDA issued a consumer alert "Stimulant Potentially Dangerous to Health, FDA Warns" warning consumers to stop using DMAA products. FDA indicated that "after reviewing the studies provided by USPLabs, FDA has found the information insufficient to defend the use of DMAA as an ingredient in dietary supplements." FDA indicated its intent to use all available legal remedies to force these illegal products from the market.

Nevertheless, USP and GNC continued to sell OxyElite with DMAA, putting consumers at further risk.

37. In June 2013, two federal courts authorized the seizure by the Department of Justice of all of GNC's DMAA products, including OxyElite with DMAA.

38. Even USP, who in a press release from April 15, 2013, agreed to phase out OxyElite with DMAA, continued to sell out its inventory. In fact, it took repeated pressure and threats from the FDA of enforcement to get USP to stop selling the illegal OxyElite with DMAA. On July 2, 2013, under threat of further legal action by FDA, USP finally agreed to destroy all of its remaining DMAA products, worth an estimated $8 million.

USP Markets OxyElite Pro New Formula, the Next Generation of Untested and Dangerous Dietary Supplements

39. USP failed to learn its lesson from OxyElite with DMAA. It continued to sell a dangerous, illegal product even under threat from the FDA, putting profits ahead of the safety of consumers.

40. As USP started to phase out OxyElite with DMAA it reformulated OxyElite. However, as before, USP failed to conduct adequate testing of the safety of OxyElite Pro New Formula. It simply threw a bunch of synthetic ingredients into a bottle and marketed the product as safe and

effective. OxyElite with DMAA had been evaluated by studies that were woefully inadequate and were funded by USP. This time around, USP decided to dispense with even sham clinical research. It simply marketed OxyElite Pro New Formula as "Scientifically Reviewed," no doubt trying to draft off its earlier studies with DMAA, an ingredient not present in OxyElite Pro New Formula. Moreover, using the phrases "Scientifically Reviewed" and "Pharmacist Formulated" misleads consumers into believing that the individual ingredients used have been thoroughly investigated and are demonstrated to be safe, when in fact, the ingredients have not been adequately tested for safety and are in fact not safe. It further misleads consumers because it suggests OxyElite Pro New Formula as a whole (with all of its numerous ingredients interacting) has been adequately tested when, in fact, it has not been tested at all. The one study that has been conducted on any ingredients in OxyElite Pro New Formula (norcoclaurine) was funded by USP using the same researcher as in the DMAA studies. It made no attempt to test safety variables such as liver function tests.[1]

[1] Lee, SR, et al., *Acute oral intake of a higenamine-based dietary supplement increases circulating free fatty acids and energy expenditure in human subjects*, 12 Lipids in Health and Disease 148 (2013).

41. Sadly, USP's cavalier marketing scheme caused many to suffer. On September 26, 2013, the Hawaii State Department of Health issued a press release stating:

> The Hawaii State Department of Health (DOH) is investigating at least 10 cases of acute liver inflammation and failure that have occurred in the state from May through September 2013. Thus far, the cases have been negative for infectious causes, have no history of engaging in high-risk social activities, and have no identified commonly expected risk factors for liver failure.
>
> The only common finding among all the cases, at this point, is the use of a dietary or nutritional supplement for the purpose of weight loss and/or muscle gain in the past six months. Cases have been reported from every county in the state.

42. Over the ensuing weeks, as healthcare providers were alerted to the connection of liver injuries to the OxyElite Pro Super Thermo and the rest of the OxyElite Pro New Formula line, the number of cases in Hawai‘i increased.

43. The FDA and CDC began to assist the Hawaii State Department of Health, and on October 8, 2013, the FDA issued a Health Advisory for OxyElite Pro New Formula, warning consumers to stop using the OxyElite Pro New

Formula. It reported 29 cases of non-viral hepatitis in which other causes had been ruled out. Of those, 24 were reported to be on an OxyElite Pro New Formula product. Two of the cases had liver transplants, one person died and 11 were hospitalized. The FDA and CDC urged healthcare providers to submit additional cases of non-viral hepatitis in which no other causes could be identified and in which the patient had reported use of OxyElite Pro New Formula to determine the full extent of the damage caused by OxyElite Pro New Formula.

44. The number of cases submitted to FDA and CDC approaches 50. On information and belief, the number of confirmed cases of liver injuries from OxyElite Pro New Formula in Hawai‘i has climbed to 27. FDA and CDC continue to evaluate cases of liver injury from OxyElite Pro New Formula occurring in the continental United States.

45. As with the old OxyElite with DMAA, USP used new, synthetic, untested and dangerous ingredients, including without limitation the untested, synthetic and illegal ingredient aegeline. On October 11, 2013, the FDA issued a warning letter to USP indicating that aegeline (N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide), an ingredient in all the OxyElite Pro New Formula products, was a new dietary ingredient that lacked evidence of safety. FDA updated the public on its continued investigation:

The FDA along with the Centers for Disease Control and Prevention (CDC) and state and local health officials are investigating more than 50 cases of acute non-viral hepatitis. As of October 31, 2013, 56 cases had been identified. Among these cases, 22 people have been hospitalized, two people have received liver transplants, and one person has died.

In a warning letter issued to USP Labs LLC of Dallas Texas on October 11, 2013, the FDA informed the company that the dietary supplements OxyElite Pro and VERSA-1 are deemed to be adulterated, and that failure to immediately cease distribution of these products may result in enforcement action by the FDA.

The warning letter states that the products are deemed adulterated because they contain a new dietary ingredient (an ingredient not previously present in the food supply, and for which there is no history of use or other evidence of safety when used as suggested in the labeling) which lacks adequate information to provide reasonable assurance of safety.

Specifically, USP Labs failed to provide the FDA with evidence, as required by law, that aegeline, also referred to as N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide, was safe for use in its dietary supplements.

By letter dated Nov. 6, 2013, the FDA notified USPlabs about findings indicating a link between the use of the above listed OxyElite Pro products and a number of liver illnesses reported in Hawaii. The FDA also noted that cases of liver damage after use of these OxyElite Pro products had been found in a number of other states.

In a review of 46 medical records submitted to the FDA by the Hawaii Department of Health, the records indicated that 27 patients, or 58 percent, had taken a dietary supplement labeled as OxyElite Pro prior to becoming ill. Seventeen of the 27 patients (or 63 percent) reported that OxyElite Pro was the only dietary supplement they were taking. One death has occurred among these patients, another patient has required a liver transplant, and others await liver transplants.

The letter also notified USPlabs that if the company did not initiate a voluntary recall, the FDA could by law order the company to immediately

stop distributing the dietary supplements and immediately notify other parties to stop distributing the dietary supplements. The action marks the second time the FDA has exercised its recall authority under the FDA Food Safety Modernization Act (FSMA) by sending such a letter.

46. In response to the outbreak, GNC continued to market OxyElite Pro New Formula. On or about October 10, 2013, the Hawaii State Department of Health ordered an embargo on the import and sale of OxyElite Pro New Formula in the state of Hawai‘i. It took threats from the Hawaii State Department of Health to get GNC to pull the products from shelves in Hawai‘i.

47. In response to the outbreak and warnings from FDA that it was illegally marketing OxyElite Pro New Formula, USP attempted to shift the blame, claiming that the injuries were caused by counterfeit products. There is no evidence that counterfeit OxyElite Pro products exist. Nor has FDA found substantiation for such a claim.

48. Although USP agreed to halt all distribution of OxyElite Pro New Formula products, it did not timely initiate a full recall of the product, instead allowing it to continue to be marketed and further exposing consumers to harm. On November 9, 2013, after FDA warned USP again that it would take all enforcement action against the illegal and unsafe OxyElite Pro New Formula, USP agreed to initiate a full-scale recall of all three versions of OxyElite Pro New

Formula. As part of its recall USP conceded that OxyElite Pro New Formula was hepatotoxic:

> Epidemiological evidence shows that use of these products has been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii. Investigations are ongoing into a potential causal relationship.

49. FDA will oversee the destruction of USP's warehoused supplies of OxyElite Pro New Formula, estimated at $22 million. FDA's director of the Division of Dietary Supplement Programs, Daniel Fabricant, Ph.D., expressed FDA's frustration with USP's recklessness:

> Twice in a short period, this company has added new dietary ingredients to supplements without notifying the FDA and providing a reasonable expectation of safety, as required by law. . . . Losses to the company should also serve as a reminder that FDA's laws and regulations serve a purpose and must be followed.

50. Despite FDA's valiant effort to quickly get OxyElite Pro New Formula off the shelves, GNC continued to market the product for months.

51. It may take months or years for the full extent of victims of this product to be realized.

USP's Failure to Use Current Good Manufacturing Processes Places Consumers at an Unreasonable Risk

52. Not only did USP fail to conduct adequate or any testing of OxyElite Pro New Formula for safety, it also failed to conduct adequate testing of products to ensure they meet current good manufacturing practices (cGMP).

53. On December 4, 2012, the FDA sent a letter to USP after a two-week inspection of USP's facilities outlining several violations of cGMP and the federal Food Drug & Cosmetic Act. For example, the FDA noted:

> **Adulterated Dietary Supplements**
>
> In addition, even if your product listed above was not an unapproved new and misbranded drug, it and the other products distributed under your firm's label would be adulterated dietary supplements within the meaning of section 402(g)(1) of the Act [21 U.S.C. § 342(g)(1)] in that the dietary supplements have been prepared, packed, or held under conditions that do not meet the requirements set forth in the Current Good Manufacturing Practice (CGMP) in Manufacturing, Packaging,

> or Holding Operations for Dietary Supplements regulation, Title 21, Code of Federal Regulations, Part 111, (21 CFR Part 111).
>
> Based on the records reviewed during this inspection, your firm sends raw materials to contract manufacturers who manufacture (b)(4) dietary supplements including Jack3d, OxyElite Pro, Prime, and Super Cissus various packaging configurations and flavors, and then return the finished products to USPlabs for distribution under your firm's own label. As a dietary supplement distributor that contracts with another contract manufacturer to manufacture dietary supplement under your firm's name, your firm is ultimately responsible for complying with the requirements relating to manufacturing operations [see 72 Fed. Reg. 34752, 34790; June 25, 2007]. Your firm has an obligation to know what and how manufacturing activities are performed so that you can make decisions related to whether your dietary supplement products conform to established specifications and whether to approve and release the products for distribution.

The FDA cited several violations, including that: 1.) USP fails to establish product specifications for the identity and purity of finished products and for limits on contaminants that may adulterate the product where it is incumbent

on them to determine what types of contamination are likely and to develop appropriate tests; 2.) USP fails to review formulas for quality control; and 3.) USP does not test raw ingredients used in its products before sending them to be manufactured by third parties.

54. These violations of cGMP and federal law placed consumers at risk for exposure to untested, contaminated ingredients. FDA, CDC and the Hawaii State Department of Health are looking into, and on information and belief, there are issues of contamination in OxyElite Pro New Formula, which are in part or in the alternative wholly responsible for Plaintiff's injuries.

COUNT I

NEGLIGENCE

(Plaintiff Against USP and DOES 1-500)

55. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

56. At all times herein mentioned, USP and DOES 1-500, and each of them, had a duty to exercise reasonable care in the research, development, testing for safety, formulation, manufacture, hiring of and use of qualified scientific or medical personnel, labeling, packaging, promotion, advertising, marketing, distribution, sale, and otherwise releasing into the stream of commerce OxyElite Pro New Formula.

57. USP and DOES 1-500, and each of them, breached their duty of reasonable care to Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled and/or sold OxyElite Pro New Formula. Specifically, USP and DOES 1-500 failed to exercise reasonable care in ways which included, but were not limited to, one or more of the following particulars:

a. In their failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff herein, of the dangerous and defective characteristics of OxyElite Pro New Formula;

b. In their failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff herein, of the propensity of OxyElite Pro New Formula to cause side effects, serious injury and death;

c. In representing that OxyElite Pro New Formula was safe and effective for its intended use when, in fact, the product was unsafe for its intended use;

d. In failing to perform appropriate, reliable and valid pre-market testing for safety of OxyElite Pro New Formula;

e. In failing to perform appropriate, reliable and valid pre-market testing for contamination or purity of OxyElite Pro New Formula;

f. In failing to perform appropriate post-market testing of OxyElite Pro New Formula;

g. In failing to disclose to consumers and Plaintiff adverse events received from FDA by users of OxyElite Pro New Formula;

h. In failing to monitor or require sterile and good manufacturing processes of OxyElite Pro New Formula;

i. In failing to adequately represent the lack of research conducted on OxyElite Pro New Formula; and

j. In failing to perform appropriate post-market surveillance of OxyElite Pro New Formula.

58. USP and DOES 1-500, and each of them, knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of the USP and DOES 1-500's failure to exercise reasonable and ordinary care.

59. As a direct and proximate result of USP and DOES 1-500s' carelessness and negligence, and of the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for

medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. The injuries and damages alleged herein are permanent and will continue into the future.

COUNT II

NEGLIGENCE

(Plaintiff Against GNC)

60. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

61. At all times herein mentioned, GNC had a duty to exercise reasonable care in the testing, packaging, promotion, advertising, marketing, distribution, sale, and otherwise releasing into the stream of commerce OxyElite Pro New Formula.

62. GNC breached its duty of reasonable care to Plaintiff in that it negligently tested, inspected, packaged, promoted, marketed, distributed, and/or sold OxyElite Pro New Formula. Specifically, GNC failed to exercise reasonable care in ways which included, but were not limited to, one or more of the following particulars:

a. In its failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff

herein, of the dangerous and defective characteristics of OxyElite Pro New Formula;

b. In its failure to warn or instruct and/or adequately warn or adequately instruct the public and consumers, including Plaintiff herein, of the propensity of OxyElite Pro New Formula to cause side effects, serious injury and death;

c. In its failure to adequately represent the lack of research with respect to OxyElite Pro New Formula;

d. In representing that OxyElite Pro New Formula was safe and effective for its intended use when, in fact, the product was unsafe for its intended use;

e. In failing to perform appropriate, reliable and valid pre-market testing of OxyElite Pro New Formula;

f. In failing to perform appropriate post-market testing of OxyElite Pro New Formula;

g. In failing to disclose to conduct any testing of OxyElite Pro New Formula before selling it to consumers; and

h. In failing to perform appropriate post-market surveillance of OxyElite Pro New Formula.

63. GNC knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of the GNC's failure to exercise reasonable and ordinary care.

64. As a direct and proximate result of GNC's carelessness and negligence, and of the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered severe and permanent injuries. Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earnings, and was otherwise physically, emotionally, and economically injured. Plaintiff suffered severe pecuniary loss. The injuries and damages alleged herein are permanent and will continue into the future.

COUNT III

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Plaintiff Against USP and DOES 1 - 500)

65. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

66. At all times material to this action, USP and DOES 1-500, and each of them, were responsible for designing, developing, manufacturing, testing,

packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities the dietary supplement OxyElite Pro New Formula, which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff.

67. At all times material to this action, OxyElite Pro New Formula was manufactured, distributed, and/or sold by USP in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained contaminants which were not intended to be a part of the product which rendered the product unreasonably dangerous when used for its intended and foreseeable purpose;

b. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained unintended or incorrect ratios or quantities of ingredients which rendered the product unreasonably dangerous when used for its intended and foreseeable purpose; and/or

c. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained

contaminants which were not intended to be a part of the product which rendered the product unreasonably dangerous and which caused it to differ from other ostensibly identical units of the same product line.

68. In light of the potential and actual risk of harm associated with the product's use, a reasonable person who had actual knowledge of this potential risk of harm would have concluded OxyElite Pro New Formula should not have been marketed in that condition.

69. At all times relevant herein, USP and DOES 1-500 knew that OxyElite Pro New Formula would be purchased by members of the general public and would be used by such purchasers without a prescription and without any inspections for defects, and would rely upon the representations made by USP and DOES 1-500 on the product label and in their marketing including public statements and promotional and sales materials.

70. At all times material to this action, OxyElite Pro New Formula was expected to reach, and did reach, consumers in the State of Hawai‘i and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

71. USP and DOES 1-500 knew or should have known of the defective nature of OxyElite Pro New Formula but continued to research, develop, design,

test, manufacture, package, formulate, inspect, label, distribute, market, promote, sell and otherwise release this product into the stream of commerce so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by their product, including liver conditions and other health problems.

72. At all times, Plaintiff used OxyElite Pro New Formula for its intended or reasonably foreseeable purpose.

73. As a direct and proximate result of the defective and unreasonably dangerous condition of OxyElite Pro New Formula and of its failure to perform safely, Plaintiff suffered injuries as set forth above.

COUNT IV

STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

(Plaintiff Against GNC)

74. Plaintiff incorporates by reference each and every prior paragraph of this

Complaint as though set forth in full in this cause of action.

75. At all times material to this action, GNC was responsible for testing, distributing, and/or selling, the dietary supplement OxyElite Pro New Formula,

which is defective and unreasonably dangerous to users and/or consumers of the drug, including Plaintiff.

76. At all times material to this action, OxyElite Pro New Formula was distributed and/or sold by GNC in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained contaminants which were not intended to be a part of the product which rendered the product unreasonably dangerous when used for its intended and foreseeable purpose;

b. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained unintended or incorrect ratios or quantities of ingredients which rendered the product unreasonably dangerous when used for its intended and foreseeable purpose; and/or

c. When placed in the stream of commerce, OxyElite Pro New Formula was of a substandard condition in that it contained contaminants which were not intended to be a part of the product which rendered the product unreasonably dangerous and which

caused it to differ from other ostensibly identical units of the same product line.

77. In light of the potential and actual risk of harm associated with the product's use, a reasonable person who had actual knowledge of this potential risk of harm would have concluded OxyElite Pro New Formula should not have been marketed in that condition.

78. At all times relevant herein, GNC knew that OxyElite Pro New Formula would be purchased by members of the general public and would be used by such purchasers without a prescription and without any inspections for defects, and would rely upon the representations made by GNC in its marketing including public statements and promotional and sales materials.

79. At all times material to this action, OxyElite Pro New Formula was expected to reach, and did reach, consumers in the State of Hawai'i and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

80. GNC knew or should have known of the defective nature of OxyElite Pro New Formula but continued to research, distribute, market, promote, sell and otherwise release this product into the stream of commerce so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of

the foreseeable harm caused by its product, including liver conditions and other health problems.

81. At all times, Plaintiff used OxyElite Pro New Formula for its intended or reasonably foreseeable purpose.

82. As a direct and proximate result of the defective and unreasonably dangerous condition of OxyElite Pro New Formula and of its failure to perform safely, Plaintiff suffered injuries as set forth above.

COUNT V

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Plaintiff Against USP and DOES 1 - 500)

83. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

84. At all times material to this action, USP and DOES 1-500, and each of them, were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities the dietary supplement OxyElite Pro New Formula, which is defective and unreasonably dangerous to users and/or consumers of the product, including Plaintiff.

85. At all times material to this action, OxyElite Pro New Formula was designed, developed, manufactured, tested, packaged, promoted, marketed,

distributed, labeled, and/or sold by USP in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, OxyElite Pro New Formula contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the product, including Plaintiff, to risks which exceeded the benefits of the product;

b. The product did not perform as safely as an ordinary consumer would have expected it to perform when used in an intended or reasonably foreseeable way;

c. The product was insufficiently tested;

d. The product caused harmful side effects that outweighed any potential utility;

e. The product was more dangerous than other dietary supplements on the market; and

f. The product was not accompanied by adequate labeling or instructions for use to fully apprise the public and consumers,

including Plaintiff, of the potential risks and serious side effects associated with its use.

86. In light of the potential and actual risk of harm associated with the product's use, a reasonable person who had actual knowledge of this potential risk of harm would have concluded OxyElite Pro New Formula should not have been marketed in that condition.

87. There existed safer alternative designs, but USP and DOES 1-500 chose to market a more dangerous design.

88. At all times relevant herein, USP and DOES 1-500 knew that OxyElite Pro New Formula would be purchased by members of the general public and would be used by such purchasers without a prescription and without any inspections for defects, and would rely upon the representations made by USP and DOES 1-500 on the product label and in their marketing including public statements and promotional and sales materials.

89. At all times material to this action, OxyElite Pro New Formula was expected to reach, and did reach, consumers in the State of Hawai‘i and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

90. USP and DOES 1-500 knew or should have known of the defective nature of OxyElite Pro New Formula but continued to research, develop, design,

test, manufacture, package, formulate, inspect, label, distribute, market, promote, sell and otherwise release these products into the stream of commerce so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by their products, including liver conditions and other health problems.

91. At all times, Plaintiff used OxyElite Pro New Formula for its intended or reasonably foreseeable purpose as a dietary workout or weight loss supplement.

92. As a direct and proximate result of the defective and unreasonably dangerous condition of OxyElite Pro New Formula and of its failure to perform safely, Plaintiff suffered injuries as set forth above.

COUNT VI

STRICT PRODUCTS LIABILITY – DESIGN DEFECT

(Plaintiff Against GNC)

93. Plaintiff incorporates by reference each and every prior paragraph of this

Complaint as though set forth in full in this cause of action.

94. At all times material to this action, GNC was responsible for testing, promoting, marketing, distributing, and/or selling, the dietary supplement OxyElite Pro New Formula, which is defective and unreasonably dangerous to users and/or consumers of the product, including Plaintiff.

95. At all times material to this action, OxyElite Pro New Formula was tested, packaged, promoted, marketed, distributed, and/or sold by GNC in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, OxyElite Pro New Formula contained unreasonably dangerous design defects and was not reasonably safe and fit for its intended or reasonably foreseeable purpose or as intended to be used, thereby subjecting users and/or consumers of the product, including Plaintiff, to risks which exceeded the benefits of the product;

b. The product did not perform as safely as an ordinary consumer would have expected it to perform when used in an intended or reasonably foreseeable way;

c. The product was insufficiently tested;

d. The product caused harmful side effects that outweighed any potential utility;

e. The product was more dangerous than other dietary supplements on the market; and

f. The product was not accompanied by adequate labeling or instructions for use to fully apprise the public and consumers,

including Plaintiff, of the potential risks and serious side effects associated with its use.

96. In light of the potential and actual risk of harm associated with the product's use, a reasonable person who had actual knowledge of this potential risk of harm would have concluded OxyElite Pro New Formula should not have been marketed in that condition.

97. There existed safer alternative designs, but GNC chose to market a more dangerous design.

98. At all times relevant herein, GNC knew that OxyElite Pro New Formula would be purchased by members of the general public and would be used by such purchasers without a prescription and without any inspections for defects, and would rely upon the representations made by GNC in its marketing including public statements and promotional and sales materials.

99. At all times material to this action, OxyElite Pro New Formula was expected to reach, and did reach, consumers in the State of Hawai‘i and throughout the United States, including Plaintiff, without substantial change in the condition in which it was sold.

100. GNC knew or should have known of the defective nature of OxyElite Pro New Formula but continued to research, test, inspect, distribute, market, promote, sell and otherwise release these products into the stream of commerce so

as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by its products, including liver conditions and other health problems.

101. At all times, Plaintiff used OxyElite Pro New Formula for its intended or reasonably foreseeable purpose as a dietary workout or weight loss supplement.

102. As a direct and proximate result of the defective and unreasonably dangerous condition of OxyElite Pro New Formula and of its failure to perform safely, Plaintiff suffered injuries as set forth above.

COUNT VII

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Plaintiff Against USP and DOES 1-500)

103. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

104. At all times material to this action, USP and Does 1-500 were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling, directly and indirectly, through third parties or related entities the dietary supplement OxyElite Pro New Formula, which is defective and unreasonably dangerous to users and/or consumers of the product, including Plaintiff.

105. At all times material to this action, OxyElite Pro New Formula was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by USP and Does 1-500 in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with OxyElite Pro New Formula, and the comparative severity, duration and the extent of the risks and reactions;

b. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the propensity to cause a substantial increased risk of serious bodily harm, specifically including but not limited to hepatitis, liver dysfunction, liver failure or other liver injuries, even in those with no known history of liver problems;

c. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous drug-drug interactions and food-drug interactions; and

d. The warnings that were given by the USP and Does 1-500 were not accurate, clear, and/or were ambiguous.

106. Plaintiff could not have discovered any defect in OxyElite Pro New Formula through the exercise of reasonable care.

107. USP and Does 1-500, as manufacturers, sellers and/or distributors of OxyElite Pro New Formula, are held to the level of knowledge of an expert in the field.

108. Plaintiff reasonably relied on the skill, superior knowledge, and judgment of USP and Does 1-500.

109. USP and Does 1-500 had a continuing duty to warn the Plaintiff of the dangers associated with the use of OxyElite Pro New Formula.

110. Plaintiff consumed and used OxyElite Pro New Formula for its intended purpose as a dietary workout and/or weight loss supplement.

111. Had Plaintiff received adequate warnings regarding the risks of OxyElite Pro New Formula, Plaintiff would not have used it.

112. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered injuries as set forth above.

COUNT VIII

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

(Plaintiff Against GNC)

113. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

114. At all times material to this action, GNC was responsible for testing, promoting, marketing, distributing, and/or selling, the dietary supplement OxyElite Pro New Formula, which is defective and unreasonably dangerous to users and/or consumers of the product, including Plaintiff.

115. At all times material to this action, OxyElite Pro New Formula was tested, packaged, promoted, marketed, distributed, and/or sold by GNC in a defective and unreasonably dangerous condition in ways which included, but were not limited to, one or more of the following particulars:

a. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous risks and reactions associated with OxyElite Pro New Formula, and the comparative severity, duration and the extent of the risks and reactions;

b. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the propensity to cause a substantial increased risk of serious bodily harm, specifically including but not limited to hepatitis, liver dysfunction, liver failure or other liver injuries, even in those with no known history of liver problems;

c. it contained warnings insufficient to alert consumers, including Plaintiff herein, of the dangerous drug-drug interactions and food-drug interactions; and

d. The warnings that were given by the GNC were not accurate, clear, and/or were ambiguous.

116. Plaintiff could not have discovered any defect in OxyElite Pro New Formula through the exercise of reasonable care.

117. GNC, as seller and/or distributor of OxyElite Pro New Formula, is held to the level of knowledge of an expert in the field.

118. Plaintiff reasonably relied on the skill, superior knowledge, and judgment of GNC.

119. GNC had a continuing duty to warn the Plaintiff of the dangers associated with the use of OxyElite Pro New Formula.

120. Plaintiff consumed and used OxyElite Pro New Formula for its intended purpose as a dietary workout and/or weight loss supplement.

121. Had Plaintiff received adequate warnings regarding the risks of OxyElite Pro New Formula, Plaintiff would not have used it.

122. As a direct and proximate result of the defective and inappropriate warnings and the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered injuries as set forth above.

COUNT IX

BREACH OF IMPLIED WARRANTY

(Plaintiff Against USP and Does 1-500)

123. Plaintiff incorporates by reference each and every prior paragraph of this

Complaint as though set forth in full in this cause of action.

124. At all times, USP and Does 1-500 impliedly warranted that OxyElite Pro New Formula was safe, effective and fit for use by consumers and users, including Plaintiff, for its intended use as a dietary weight loss and/or workout supplement, that it was of merchantable quality, that it did not produce dangerous side effects, and that it was adequately tested and fit for its intended purpose.

125. At the time of making these warranties, USP and Does 1-500 knew or should have known that, in fact, the representations and warranties were false, misleading, and untrue in that OxyElite Pro New Formula was not safe, effective and fit for use by consumers and users, including Plaintiff, for its intended use as a dietary weight loss and/or workout supplement, that it was not of merchantable quality, that it did produce dangerous side effects including liver dysfunction, hepatitis, liver failure and other injuries as herein alleged, and that it was not adequately tested or fit for its intended purpose.

126. Members of the public, including Plaintiff, reasonably relied upon the skill and judgment of USP and Does 1-500 and upon said implied warranties in using OxyElite Pro New Formula.

127. Plaintiff used OxyElite Pro New Formula for its intended purpose as a dietary weight loss and/or workout supplement.

128. USP and Does 1-500 breached said implied warranties, in that, OxyElite Pro New Formula was not safe, effective and fit for its intended purpose as a dietary weight loss and/or workout supplement, was not of merchantable quality, and, in fact, caused serious and potentially lethal side effects to consumers when taken in its recommended dose, including liver dysfunction, hepatitis, liver failure and other injuries as herein alleged.

129. Due to USP and Does 1-500's wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with OxyElite Pro New Formula until after he used it.

130. As a direct and proximate result of the USP and Does 1-500's breach of implied warranties and the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered injuries as set forth above.

COUNT X

BREACH OF IMPLIED WARRANTY

(Plaintiff Against GNC)

131. Plaintiff incorporates by reference each and every prior paragraph of this

Complaint as though set forth in full in this cause of action.

132. At all times, GNC impliedly warranted that OxyElite Pro New Formula was safe, effective and fit for use by consumers and users, including Plaintiff, for its intended use as a dietary weight loss and/or workout supplement, that it was of merchantable quality, that it did not produce dangerous side effects, and that it was adequately tested and fit for its intended purpose.

133. At the time of making these warranties, GNC knew or should have known that, in fact, the representations and warranties were false, misleading, and untrue in that OxyElite Pro New Formula was not safe, effective and fit for use by consumers and users, including Plaintiff, for its intended use as a dietary weight loss and/or workout supplement, that it was not of merchantable quality, that it did produce dangerous side effects including liver dysfunction, hepatitis, liver failure and other injuries as herein alleged, and that it was not adequately tested or fit for its intended purpose.

134. Members of the public, including Plaintiff, reasonably relied upon the skill and judgment of GNC and upon said implied warranties in using OxyElite Pro New Formula.

135. Plaintiff used OxyElite Pro New Formula for its intended purpose as a dietary weight loss and/or workout supplement.

136. GNC breached said implied warranties, in that, OxyElite Pro New Formula was not safe, effective and fit for its intended purpose as a dietary weight loss and/or workout supplement, was not of merchantable quality, and, in fact, caused serious and potentially lethal side effects to consumers when taken in its recommended dose, including liver dysfunction, hepatitis, liver failure and other injuries as herein alleged.

137. Due to GNC'S wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with OxyElite Pro New Formula until after they used it.

138. As a direct and proximate result of the GNC'S breach of implied warranties and the unreasonably dangerous and defective characteristics of OxyElite Pro New Formula, Plaintiff suffered injuries as set forth above.

Punitive Damages Allegations

(Plaintiff Against USP)

(Plaintiff Against GNC)

139. Plaintiff incorporates by reference each and every prior paragraph of this Complaint as though set forth in full in this cause of action.

140. Beginning with OxyElite with DMAA, USP and GNC engaged in a course of conduct that included using synthetic ingredients, lying about using synthetic ingredients, selling untested or inadequately tested products containing synthetic ingredients, misrepresenting the safety and efficacy of those products, continuing to market products despite known safety concerns raised by federal agencies and otherwise engaging in a course of conduct that is reprehensible. That conduct continued with the marketing of OxyElite Pro New Formula.

141. At all times material hereto, USP and GNC knew that the use of OxyElite Pro New Formula could result in the development of serious harm and death. Additionally, USP and GNC knew that the use of OxyElite Pro New Formula would cause certain susceptible users, including Plaintiff, to suffer serious injury, such as hepatitis, liver failure and death.

142. At all times material hereto, USP and GNC engaged in conduct that constitutes malice, oppression or fraud, including without limitation the misrepresentations, warranties and omissions set forth above.

143. USP and GNC continued to aggressively market OxyElite Pro New Formula to consumers, including Plaintiff, without disclosing the fact that use of OxyElite Pro New Formula could result in the development of serious injuries, that it was ineffective, that it was not made from natural ingredients, that OxyElite Pro New Formula was liver toxic, even in individuals with no known liver conditions,

that FDA considered OxyElite Pro New Formula and aegeline illegal, that FDA, CDC and the Hawaii State Department of Health had received numerous adverse reports from users of OxyElite Pro New Formula, and other information about the safety of OxyElite Pro New Formula. USP and GNC did so knowing that their failure to reveal the probable consequences of ingesting OxyElite Pro New Formula would seriously injure or kill consumers, including Plaintiff, in order to make a profit and in so doing they acted with malice.

144. USP and GNC went further than failing to warn of OxyElite Pro New Formula's defective and dangerous nature. They intentionally and falsely represented and warranted that OxyElite Pro New Formula was safe when they knew that, in fact, OxyElite Pro New Formula was unsafe and posed a serious risk of injury to consumers, including Plaintiff. They further concealed the true risks of OxyElite Pro New Formula as alleged herein. They further represented that counterfeit versions of OxyElite Pro New Formula were on the market to divert attention from the risks of OxyElite Pro New Formula, knowing there were not such counterfeit products. In so doing, they acted with fraud.

145. USP and GNC continued to sell OxyElite Pro New Formula despite the Hawaii State Department of Health's warning that the product was linked to numerous liver injuries. GNC continued to sell OxyElite Pro New Formula despite a request from the Hawaii State Department of Health to cease sales and despite a

warning from the FDA to consumers to stop using the product and despite the fact the product was illegal. Such conduct is despicable and oppressive.

146. USP and GNC's acts of malice, oppression and fraud were on the part of corporate officers, directors or managing agents, or were on the part of employees and were ratified or authorized by USP and GNC, respectively.

147. USP and GNC's intentional and/or reckless failure to disclose information deprived Plaintiff of necessary information to enable Plaintiff to weigh the true risks of OxyElite Pro New Formula against the benefits in making his decision to use OxyElite Pro New Formula.

148. As a direct and proximate result of the USP and GNC's conscious and deliberate disregard for the rights and safety of consumers, Plaintiff suffered severe injury and loss. Plaintiff likewise suffered loss as alleged herein. Plaintiff seeks actual and punitive damages from USP and GNC as alleged herein.

149. The aforesaid conduct of the USP and GNC was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff herein, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish USP and GNC and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

a. As to all Counts and all DEFENDANTS, damages to the Plaintiff according to proof including as applicable:

i. Past and future medical and care expenses of Plaintiff according to proof;

ii. Past and future loss of earnings (and/or profits) of Plaintiff according to proof;

iii. Other economic loss;

b. As to all Counts and all DEFENDANTS, Non-economic damages according to proof including as applicable:

i. Compensation for physical pain and discomfort;

ii. Compensation for fright, nervousness, anxiety, worry, and apprehension;

c. As to all Counts and all DEFENDANTS, awarding pre-judgment and post-judgment interest to the Plaintiff according to proof;

d. As to all Counts and all DEFENDANTS, awarding reasonable costs to the Plaintiff as provided by law;

e. As to Counts III-X and USP and GNC, awarding Plaintiff punitive and treble damages; and

f. As to all Counts and all DEFENDANTS, granting all such other relief as the Court deems necessary, just and proper.

DATED: Honolulu, Hawaii June 17, 2015.

/s/ Wayne Parsons
WAYNE PARSONS
Attorney for Plaintiff